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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/555,074	10/28/2005	Kazuhisa Sugimura	64395(70904)	3084

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EXAMINER
JIANG, DONG

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/555,074	SUGIMURA ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,18,20,21,25-27,29 and 30* is/are pending in the application.

4a) Of the above claim(s) *30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16,18,20,21,25-27 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-16,18,20,21,25-27,29 and 30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :10/28/05, 2/21/06, 3/23/07, 5/29/07, 6/25/07 & 8/1/07.

DETAILED OFFICE ACTION

Applicant's election of Group I invention filed on 24 July 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's amendment filed on 24 July 2007 is acknowledged and entered. Following the amendment, claims 17, 19 and 28 are canceled, and claim 4 is amended.

Currently, claims 1-16, 18, 20, 21, 25-27, 29 and 30 are pending, and claims 1-16, 18, 20, 21, 25-27 and 29 are under consideration. Claim 30 is withdrawn from further consideration as being drawn to a non-elected invention.

Formal Matters:

Information Disclosure Statement

Applicant's IDSs submitted on 8/1/07, 6/25/07, 5/29/07, 3/23/07, 2/21/06 and 10/28/05 are acknowledged and have been considered. A signed copy is attached hereto.

Priority acknowledgement

This application is a national stage entry (371) of PCT/JP04/06403 with the international filing date of 4/30/04, which is acknowledged.

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on 30 April 2003, in a language other than English. It is noted that applicant has not filed an English language translation. Applicants are reminded that an English language translation of a non-English language foreign application is required when necessary to overcome the date of a reference relied upon by the examiner (37 CFR 1.55 (a) (4)).

Claims

Claim 16 is objected to for encompassing a non-elected subject matter, part (iii) a low-molecular weight compound. The applicant is required to amend the claims to read only upon the elected invention.

Claims 4, 7, 14 and 21 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

With respect to claim 4, the claim depends from claim 1, 2 or 3, which are directed to a human antibody with specifically defined sequences. However, the dependent claim 4 is directed to variants of those sequences, which encompass antibody polypeptides not included in the independent claims 1-3 (the scope of claim 4 is broader). Thus, claim 4 can be infringed by antibody polypeptides that do not infringe claims 1-3. Applicants attention is directed to the "Infringement Test" for dependent claims in MPEP § 608.01(n). The test for a proper dependent claim is whether the dependent claim includes every limitation of the parent claim, and a proper dependent claim shall not conceivably be infringed by anything, which would not also infringe the basic claim. Based on such, the present claims are improperly dependent, and should be rewritten in independent form.

With respect to claim 7, it depends from claim 1, 2, 3 or 5, which is drawn to an antibody and is not further limited by claim 7, which pertains to a gene.

With respect to claim 14, it depends from claim 13, which is drawn to a kit, and the product is not further limited by the method of claim 14.

With respect to claim 21, it depends from claim 18 or 20, which is drawn to an agent, and the product is not further limited by the limitation as to what it is applied to in claim 21.

Applicant is advised that should claim 15 be found allowable, claim 18 will be objected to; and that should claim 16 be found allowable, claim 29 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else

are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Rejections under 35 U.S.C. §101 and §112:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-10, 12, 15, 16, 18, 20, 21, 25, 26 and 29 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1-3, 5 and 15, *as written*, do not sufficiently distinguish over antibodies or the encoding genes as they may exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "isolated" or "purified". See MPEP 2105.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 6-16, 18, 20, 21, 25-27 and 29 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite for the recitation "ligation of a polypeptide …; and ligation of a polypeptide …" because it is unclear what the term "ligation" is meant here, and to what and how it is ligated.

Claim 4 is indefinite because of the following: it depends from claim 1, 2 or 3, which recites "an human antibody comprising a polypeptide *consisting of* an amino acid sequence … SEQ ID NO:3" (claim 2, for example). Thus, it is unclear how the antibody consists of SEQ ID NO:3, and

meanwhile, has "one or more amino acids of which are substituted, deleted, inserted, or added"; or if the limitation means the variations outside of the recited sequences since the antibody "comprising" (open) a polypeptide. The metes and bounds of the claim, therefore, cannot be determined.

Claim 6 is indefinite because it is unclear what the terms "a modified antibody" and "a modification agent" are meant, and how the modification agent *bind* to the antibody, covalently or through affinity, forming a complex? The metes and bounds of the claim, therefore, cannot be determined.

Claim 8 is indefinite for the recitation "a *base* sequence" because it is unclear what the term is meant, and how it differs from "a sequence". "Comprising, as an open reading frame, the nucleic acid sequence of SEQ ID NO:1 or 7" is suggested.

Claim 12 is indefinite for the recitation "the detector *using* either (1) the antibody …, or …" because it is unclear what it is meant, and how the detector uses the antibody, or the antibody is a part of the detector? The claim is further indefinite for the recitation "a modified antibody", "a modification agent", and "binding thereto" for the same reasons above.

Claim 13 is indefinite because a kit claim, by definition, must contain two or more elements, *and* the interrelationships between the elements must be explicitly stated (see In re Venezia, 530 USPQ 2d 956 (CCPA 1975)). The claim only recites one element (item (1) or (2)), and therefore, the claim is an improper kit claim. The claim is further indefinite for the recitation "an … kit …, *by using* either (1) …, or (2) …" because it is unclear what it is meant. "Comprising" is suggested. The claim is further indefinite for the recitation "a modified antibody", "a modification agent", and "binding thereto" for the same reasons above.

Claim 14 is indefinite for the recitation "a method for diagnosing … disease in accordance with an amount of IL-18 … in a test sample and measured by …" because it is unclear what it is meant.

Claim 15 is indefinite for the recitation "as an active ingredient" because it is unclear whether said IL-18 antagonist is the only *active* ingredient, or there are other active ingredients, and what they are. The article "the" is suggested if only IL-18 antagonist is intended.

Claim 16 is indefinite for the recitation "a modified antibody", "a modification agent", and "binding thereto" for the same reasons above.

Claim 21 is indefinite for the recitation "chronic immune abnormality disease" because neither the specification nor the claim defines such, and it is unclear what the term encompasses.

Claim 27 is indefinite for failing to adequately point out what applicants see as the invention, because it is unclear whether "a human antibody" is the same as that expressed by the gene according to claim 8. The claim should be amended to indicate the identity of the polypeptide being produced. The claim is further indefinite because it is unclear how *a* host can express the gene, is the host a cell or an animal transfected with said gene?

The remaining claims are included in this rejection because they are dependent from the specifically mentioned claims without resolving the indefiniteness issue belonging thereto.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-7, 9-12, 14-16, 18, 20, 21 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Ghayur et al. (WO 01/589565 A2, Aug. 16, 2001, provided by applicants).

Ghayur discloses antibodies to human IL-18, and pharmaceutical compositions thereof, wherein the antibodies are entirely human antibodies, have high affinity for hIL-18 and neutralize hIL-18 activity, and are useful for detecting hIL-18 and for inhibiting hIL-18 activity in a human subject suffering from a disorder in which hIL-18 activity is detrimental, such as diseases involving immune and inflammatory elements (abstract, page 4, lines 12-16, and page 22, lines 26-28). Additionally, Ghayur teaches that an antibody may be part of a larger immunoadhesion molecules including use of a marker peptide and a C-terminal poly-His tag (page 17, lines 3-9). Therefore, the reference anticipates claims 5, 6, 12, 15, 16, 18, 20, 21 and 29. Note, a limitation such as "a immunological disease treatment agent" (claims 18 and 29, for example) is merely of an intended use, which does not alter the nature of the composition. Therefore, such a limitation adds no patentable weight to said composition. Further, Ghayur teaches an isolated nucleic acid encoding the antibody, an expression vector containing the

nucleic acid, a host cell thereof, and a method of using the host cell for producing the antibody binding hIL-18 (page 5, lines 4-12). Thus, the reference anticipates claims 7 and 9-11. Furthermore, Ghayur further teaches a method for detecting hIL-18 in a biological sample with said antibody (page 33, lines 6-10), and that a disorder in which hIL-18 activity is detrimental may be evidenced by an increase in the concentration of IL-18 in a biological fluid of a subject suffering from the disorder, which can be detected using said anti-IL-18 antibody (page 35, lines 7-11), indicating a method of diagnosis using the antibody. As such, the reference also anticipates claim 14. Note, claim 14 merely require the use of the detecting *reagent* of the kit of claim 13, which is a modified antibody, and is taught by Ghayur (see above).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ghayur et al. (WO 01/589565 A2), as applied to claims 5-7, 9-12, 14-16, 18, 20, 21 and 29 above.

The teachings of Ghayur are reviewed above. Ghayur does not specifically mention a kit comprising said human anti-hIL-18 antibody.

However, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to make a kit containing Ghayur's human antibody, because such kit

would facilitate its commercial distribution, and clinical practice. Additionally, packing of useful drugs in kits is old and well known in the art.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Ruben et al. (US7,138,501) discloses an antibody polypeptide, which amino acid sequence of SEQ ID NO:1919 comprises the present SEQ ID NO:3 with 79% sequence similarity (see computer printout of the search results).

Deshpande et al. (US2003/0103978 A1) discloses an antibody polypeptide, which amino acid sequence of SEQ ID NO:73 is 97% identical to the present SEQ ID NO:9, and comprises the present SEQ ID NO:11 and 12 with 100% sequence similarity, and SEQ ID NO:10 with one amino acid mismatch (K → Q at position 30, see computer printout of the search results).

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dong Jiang

Dong Jiang, Ph.D
Patent Examiner
AU1646
9/14/07